

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

1. (Currently Amended) A process for preparing a controlled release tablet of potassium chloride comprising:

- (a) microencapsulating potassium chloride crystals with an inner membrane ~~of comprising~~ ethylcellulose by coacervation or phase separation to form potassium chloride microcapsules;
- (b) coating said potassium chloride microcapsules with an outer membrane comprising a plasticized polymer to form compressible coated microcapsules;
- (c) preparing a compressible blend comprising said compressible coated microcapsules, microcrystalline cellulose, ~~a disintegrant~~ and colloidal silicon dioxide; and
- (d) compressing said compressible blend into tablets,

wherein the tablet hardness is at least about 14 kP, the friability of the tablets does not exceed about 0.3%, ~~the tablet rapidly disperses into granules on contact with water~~ and the tablets exhibits a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

- after 2 hours, about 30% to about 50% of the total potassium chloride is released;
- after 4 hours, about 60% to about 75% of the total potassium chloride is released; and
- after 8 hours, not less than 80% of the total potassium chloride is released.

2. (Currently Amended) The process of claim 1, wherein said compressible blend further comprises a disintegrant ~~is selected from the group consisting of sodium starch glycolate, Croscarmellose sodium, cross linked polyvinylpyrrolidone, and combinations thereof.~~

3. (Previously Presented) The process of claim 2 wherein said disintegrant is present in an amount of from about 0.5% to about 5.0% by weight based on the tablet weight.

4. (Previously Presented) The process of claim 1 wherein said plasticized polymer comprises a

polymer selected from the group consisting of ethylcellulose, polyvinylpyrrolidone and hydroxypropyl methylcellulose.

5. (Previously Presented) The process of claim 4 wherein said plasticized polymer comprises ethylcellulose and said coating step comprises coating said potassium chloride microcapsules with an aqueous dispersion of ethylcellulose.

6. (Original) The process of claim 5 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate.

7. (Previously Presented) The process of claim 1 wherein said microcrystalline cellulose comprises not more than about 15% by weight of said tablet.

8. (Currently Amended) The process of claim 1 wherein the inner membrane of ethylcellulose comprises an ethylcellulose having a viscosity between about 90 cps and about 110 cps.

9. (Original) The process of claim 8 wherein said ethylcellulose forming the inner membrane comprises between about 8% and about 20% by weight of said potassium chloride microcapsules.

10. (Previously Presented) The process of claim 1 wherein said colloidal silicon dioxide is present in an amount of from about 0.1% to about 0.3% by weight of said tablet.

11. (Original) The process of claim 3 wherein said compressible blend further comprises from about 0.1% to about 1.0% of a surfactant based on the weight of said tablet.

12. (Original) The process of claim 1 wherein said plasticized polymer comprises a plasticizer selected from the group consisting of dibutyl sebacate, diethyl phthalate, triacetin, triethyl citrate, polyethylene glycols of different molecular weights and mixtures thereof.

13. (Original) The process of claim 12 wherein said plasticizer comprises from about 2% to 40% based on the weight of the plasticized polymer.

14. (Original) The process of claim 1 wherein said outer membrane coating comprises from about 0.5% to about 5.0% by weight of said compressible coated microcapsules.

15. (Previously Presented) The process of claim 1 wherein said plasticized polymer comprises hydroxypropyl methylcellulose and polyethylene glycol 400.

16. (Original) The process of claim 1 wherein said compressible blend is substantially free of lubricants.

17. (Currently Amended) The process of claim 1 wherein said plasticized polymer comprises ethylcellulose and diethyl phthalate, and said ~~outer membrane~~ compressible coated microcapsules comprises from about 0.5% to about 5% by weight of said ~~compressible-coated microcapsules~~ outer membrane, and said compressible blend comprises about 0.1% to 0.2% by weight colloidal silicon dioxide and not more than about 15% by weight of said microcrystalline cellulose.

18. (Currently Amended) The process of claim 17, wherein said compressible blend further comprising a disintegrant is present in an amount of from about 0.5% to about 3% by weight of said compressible blend.

19. (Original) A controlled release potassium chloride tablet prepared by the process of claim 1.

20. (Currently Amended) A controlled release potassium chloride tablet comprising:
_____ a) a plurality of ~~compressible-coated potassium chloride~~ microcapsules wherein said microcapsules comprise a potassium chloride crystal, an inner membrane on said crystal comprising ethyl cellulose, and an outer membrane surrounding said inner membrane comprising

a plasticized polymer;

_____ b) colloidal silicone dioxide; and

_____ c) microcrystalline cellulose,

wherein the tablet hardness is at least about 14 kP, the friability of the tablets does not exceed about 0.3%, ~~the tablet rapidly disperses into granules on contact with water and~~ the tablets exhibits a dissolution profile substantially corresponding to the following pattern when tested by USP Apparatus 2 (Paddles @ 50 rpm) in purified water:

after 2 hours, about 30% to about 50% of the total potassium chloride is released;

after 4 hours, about 60% to about 75% of the total potassium chloride is released; and

after 8 hours, not less than 80% of the total potassium chloride is released.

21. (Previously Presented) The controlled release potassium chloride tablet of claim 20 wherein said inner membrane comprises between about 8% and about 20% by weight of said microcapsules.

22. (Previously Presented) The controlled release potassium chloride tablet of claim 20 wherein said plasticized polymer comprises a polymer selected from the group consisting of ethyl cellulose, polyvinylpyrrolidone and hydroxypropylmethylcellulose.

23. (Currently Amended) The controlled release potassium chloride tablet of claim 21 wherein said ~~outer membrane coating~~ microcapsules comprises from about 0.5% to about 5.0% by weight of said ~~compressible coated microcapsules~~ outer membrane.

24. (Original) The controlled release potassium chloride tablet of claim 20 wherein said tablet further comprises a disintegrant.

25. (Currently Amended) The controlled release potassium chloride tablet of claim 24 wherein said ~~disintegrant comprises~~ is selected from the group consisting of sodium starch glycolate.

croscarmellose sodium, cross-linked polyvinylpyrrolidone.

26. (Original) The controlled release potassium chloride tablet of claim 20 wherein the potassium chloride is present in an amount effective for the treatment of potassium deficiency in humans by oral administration.

27. (Original) The controlled release potassium chloride tablet of claim 20 wherein said tablet is substantially free of lubricants.

28. (Original) The controlled release potassium chloride tablet of claim 20 wherein said plasticized polymer comprises ethyl cellulose and diethyl phthalate.

29. (Currently Amended) A method of treating potassium deficiency in a subjects in need of potassium, comprising administering to the subject an effective amount of the controlled release potassium chloride tablet of claim 20.

30. (Previously Presented) The controlled release potassium chloride tablet of claim 20, wherein said colloidal silicon dioxide is present in an amount of from about 0.1% to about 0.3% by weight of the total tablet weight.

31. (Currently Amended) The controlled release potassium chloride tablet of claim 20, wherein said microcrystalline cellulose is present in an amount of not more than about 15% by weight of the total tablet weight.

32. (New) The process of claim 2, wherein said disintegrant is selected from the group consisting of sodium glycolate, croscarmellose sodium, cross-linked polyvinylpyrrolidone, and combinations thereof.

33. (New) The controlled release potassium chloride tablet of claim 20, further comprising a disintegrant and optionally a surfactant, wherein said tablet is substantially free of lubricants.

34. (New) The controlled release potassium chloride tablet of claim 20, wherein said plasticized polymer comprises a plasticizer selected from the group consisting of dibutyl sebacate, diethyl phthalate, triacetin, triethyl citrate, polyethylene glycols of different molecular weights, and mixtures thereof.

35. (New) The controlled release potassium chloride tablet of claim 20, wherein said plasticized polymer comprises from about 2% to 40% of the plasticizer.